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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,920	04/03/2001	Ronald G. Udell	40524-SGTI	3656

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	10

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/825,920	Udell et al.
Examiner	**Art Unit**
Randall Winston	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) *1-3 and 18* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4) ☐ Interview Summary (PTO-413) Paper No(s). _
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a method for improved absorption and beneficial effects of corosolic acid for maintenance of blood sugar levels and weight-loss with the administration of an effective amount of corosolic acid, rice bran oil and silica, classified in class 424, subclass 725, for example.

II. Claims 4-17, drawn to a soft capsule including corosolic acid, rice brain oil, yellow bee's wax, silica and an extract of *Gymenma Sylvestre*, classified in class 424, subclass 400, for example.

III. Claims 18, drawn to a method for manufacture of a soft gel capsule for absorption of corosolic acid into a human intestinal tract for maintenance of blood sugar levels, classified in class 424, subclass 439, for example.

2. The inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These claimed methods, Inventions I and III, are

distinguishable, each from the other, because they are two different methods. These two methods' preambles and/or objectives are either a method of administrating a product (i.e Invention I) or a method of preparing a product (i.e. Invention III). These two different methods utilize different steps and/or approaches to achieve its preamble objective Moreover, the claimed composition is distinguishable from the methods because the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process using the product as claimed (i.e. Invention I) can be practiced with another materially different product from Invention II' product, such as with just utilizing the products extracted from *Gymnema sylvestre* for maintenance of blood sugar levels. Therefore, Inventions I-III are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. In addition, one would not have to practice the various methods and/or use of the composition at the same time to practice just one method alone and/or one composition alone.

3. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or

even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

4. During a telephone conversion with Scott Rosenberger on July 22, 2003 a provisional election was made with traverse to prosecute the invention of Group II, claims 4-17. Affirmation of this election, drawn to a soft gel capsule, must be made by applicant in replying to this Office Action. Claims 1-3 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is made vague and indefinite by the word "and." Applicant may overcome the rejection by replacing "and" with "for."

Claim 4 recites the terms "maintenance of blood sugar levels." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning "maintenance of blood sugar levels." There is no definition of "maintenance of blood sugar

levels" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Therefore, applicant may overcome this rejection by clearly delineating the metes and bonds of what is "maintenance of blood sugar levels." (Is applicant decreasing or increasing blood sugar levels?)

Claims 4, 7-11, 13-14 and 17 are made vague and indefinite by the term "including." One of ordinary skill in the art would not know how the delineate the metes and bounds of the term "including." Applicant may over come this rejection by clearly delineating the metes and bounds of the term "including." (Does "including" mean comprising or consisting ?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuyama (US 6485760) in view of Hoffman (The Complete Illustrated Herbal, *Practical Herbalism, The Preparation of Herbs*, 1996, page 20-33)

Applicant claims a soft gel capsule including (?) corosolic acid.

Matsuyama teaches an oral composition for an increase in or lowering of blood sugar levels in a patient comprising a powdered herbal extract containing corosolic acid. Matsuyama does not expressly teach that corosolic acid is contained within a soft gel capsule as an active ingredient therein. (see, e.g., abstract, claim 5)

Hoffman beneficially teaches that the easiest way to take dry powdered herbs internally is to use soft gel capsules.

It would have been obvious to one of ordinary skill in the art of creating the claimed invention to modify Matsuyama 's powdered herbal extract containing corosolic acid to include Hoffman's beneficial teachings of the easiest way to take dry powdered herbs internally is to use soft gel capsules whereas the combined teachings would obtain an improved claimed invention soft gel composition comprising corosolic acid to be administered for the maintenance of blood sugar levels and weight-loss. Furthermore, the adjustment of other conventional working conditions (e.g., the amount of corosolic acid contained within a soft gel capsule), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuyama in view of Hoffman, McPeak et al. (US 6303586), LaGrone (US 6407068), Matsutani et al. (US 5552427), and Shanmuyasundam et al. (US 5980902).

Applicant claims a soft gel capsule including(?) corosolic acid, rice bran oil, silica, yellow bee's wax and an extract of *Gymnema sylvestre* in various amounts.

Matsuyama teaches an oral composition for an increase in or lowering of blood sugar levels in a patient comprising a powdered herbal extract containing corosolic acid. Matsuyama does not expressly teach active ingredients such as corosolic acid, rice bran oil, silica, yellow bee's wax and an extract of *Gymnema sylvestre* are contained within the soft gel capsule to be administered.

Hoffman beneficially teaches that the easiest way to take dry powdered herbs internally is to use soft gel capsules.

McPeak et al. beneficially teach rice bran oil to control blood glucose levels. (see, e.g. column 7 lines 52-65).

LaGrone beneficially teaches silica for prevent diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes. (see, e.g. column 4 lines 11-14).

Shanmuyasundam et al. beneficially teach an extract of *Gymnema sylvestre* for controlling blood sugar to prevent obesity. (see, e.g. column 3 lines 16-20).

Matsutani et al. beneficially teach tablets were polished with yellow bees wax to give coated tablets. (see, e.g., column 20 lines 9-10).

It would have been obvious to one of ordinary skill in the art of creating the claimed invention to modify Matsuyama 's oral powdered composition teachings to include Hoffman's beneficial oral soft gel teachings (note: the yellow bees wax taught by Matsutani is being utilized to coat the soft gel capsule) and also to include other beneficial teaching taught by McPeak, LaGrone, and Shanmyasundam whereas McPeak, LaGrone, and Shannmyasundam's active ingredients are each being utilized for the maintenance of blood sugar levels to obtain an improved claimed invention soft gel composition to be administered for the maintenance of blood sugar levels and weight-loss. Furthermore, the result-effective adjustment of conventional working conditions therein (e.g., the amount of each active ingredient contained within a soft gel capsule), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER